(M161Ag) having a polynucleotide sequence (SEQ. ID:1) or gene recombination products thereof, wherein the induced cytokines are selected from the group consisting of: interleukin-1β, tumor necrosis factor-α, interleukin-6, interleukin-10, interleukin-12, and interferon-γ.

3. The cytokine inducers according to claim 1, wherein the cytokine inducers are used as immunomodulators.

5. The cytokine inducers according to claims 1, 3 or 4, wherein the protein M161Ag or gene recombination products thereof are acylated with fatty acid in the N-terminal thereof.

REMARKS

Claims 2 and 6-10 have been cancelled, and claims 1, 3 and 5 have been amended. The specification has been amended merely to provide a description of the sequence identifiers (SEQ. ID:1 and SEQ ID:2). No new matter has been added by virtue of the amendments made to the claims, support therefore being found throughout the specification.

Applicants also submit the amendments may be properly entered at this time, i.e., after final rejection pursuant to 37 C.F.R. § 1.116 because the amendments do not raise any new issues or require a new search and they reduce the issues for appeal. For instance, the claims as amended herein are within the scope of prior searches. It is also believed the application is in condition for allowance. Entry of the amendments is earnestly solicited.

Applicants respectfully request reconsideration of the application in light of the above amendments and the following discussion.

Claims 1-10 stand rejected under 35 USC §112, first paragraph. As the rejection is understood, in order to comply with the written description guidelines, the specification must describe and the claims recite the appropriate sequence identifiers for M161Ag.

Applicants believe that the amendments submitted herein obviate the rejection. In particular, the specification has been amended to provide a description of SEQ. ID:1 and SEQ. ID:2. Additionally, claim 1 has been amended to reference the relevant SEQ ID number.

Reconsideration and withdrawal of the rejection are thus requested.

Claims 1-10 stand further rejected under 35 USC §112, first paragraph, on the grounds that the specification allegedly does not provide enablement commensurate in scope with the present claims.

The Office Action acknowledges that the specification is enabling for cytokine inducers comprising a protein M161Ag for induction of the following list of cytokines: IL-1β, TNF-α, IL-6, IL-10, IL-12, and IFN-γ. However, the position is taken that the specification is allegedly non-enabling for induction of *all cytokines* by M161Ag. Further, the position is taken that the specification is allegedly non-enabling for use of the noted induced groups of cytokines as immunomodulators for *any immunological diseases*.

The rejection is traversed.

As an initial matter, Applicants wish to note that the M161Ag antigen is of a bacterial nature rather than fungal as stated in the Office Action. *Mycoplasma fermentans* is an intracellular parasitic bacterium, which is positive in patients with certain immunosuppressive diseases and disorders, for example, HIV, cancer such as leukemia and myeloma, and aplastic anemia. (See, e.g., the related discussion at page 1, lines 13-19 of the present application.)

Additionally, the cytokines induced by the M161Ag protein of the present invention have known bioactivities. It follows that the cytokine inducers of the present invention are highly

useful in the treatment of many immunological diseases.

For example, IL-1 is known to activate T cells and neutrophils, as well as to stimulate anti-tumor activity, and to proliferate fibroblasts and increase ACTH and GH. TNF-α is involved in the proliferation and differentiation of cells and also exhibits tumor necrosis activity. TNF-α also has been reported to increase production of prostaglandins and platelet activating factor, and to possess anti-viral activity.

Additionally, IL-6 is involved in the stimulation of B cells, and in antibody production. IL-6 also is known to stimulate differentiation and proliferation of T cells and macrophages. IL-10 is useful for control of Th1 polarization and T-cell-proliferating acceleration. IL-12 activates cytotoxic T cells (CTL) and NK cells. (See, e.g., the related discussion at page 5, lines 1-19 of the present application.) Still further, INF-γ is known to have antiviral activity.

It is respectfully submitted that the present application provides ample support and enablement to one skilled in the art, such that the full scope of the present invention could be practiced for the treatment of various immunological diseases and cancers by inducing cytokines using M161Ag.

However, while Applicants disagree with the instant rejection, it also is submitted that the rejection is obviated by the amendments herein. In particular, in order to expedite prosecution of the application, independent claim 1 has been amended to list the particular cytokines: IL-1β, TNF-α, IL-6, IL-10, IL-12, and IFN-γ. Claims 3 and 5 have been amended merely to correct informalities, and claims 2 and 6-10 have been cancelled.

In view thereof, reconsideration and withdrawal of the rejection are requested.

It is believed the application is in condition for immediate allowance, which action is

earnestly solicited.

Respectfully submitted,

Christine C. O'Day (Reg. No. 38,256)
Edward J. Adamson (Reg. No. 50,927)
EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02209
Tel. (617) 439-4444

VERSION MARKED TO SHOW CHANGES

(Additions are underlined and deletions are bracketed in bold type.)

IN THE SPECIFICATION

Kindly insert the following sentence as a separate paragraph at page 6, between lines 4 and 5:

The protein of *Mycoplasma fermentans*, M161Ag, generally comprises a polynucleotide sequence (SEQ. ID:1) and a polypeptide sequence with lipid (SEQ. ID:2).

IN THE CLAIMS

Claims 2, 6-10 were cancelled without prejudice.

The following claims were amended as follows:

1. (Twice Amended) Cytokine inducers comprising a protein *Mycoplasma fermentans* 161 Ag (M161Ag) having a polynucleotide sequence (SEQ. ID:1) or gene recombination products thereof, wherein the induced cytokines are selected from the group consisting of: interleukin-1β, tumor necrosis factor-α, interleukin-6, interleukin-10, interleukin-12, and interferon-γ.

3. (Amended) The cytokine inducers according to [any one of claims 1-4] claim 1, wherein the cytokine inducers are used as immunomodulators.

5. (Amended) The cytokine inducers according to claim 1[or 2], 3 or 4, wherein the protein M161Ag or gene recombination products thereof are acylated with fatty acid in the N-terminal thereof.